



# Chemical Right to Know High Production Volume Challenge Program Fact Sheet on Animal Welfare

## The HPV Challenge Program

The goal of the HPV Challenge Program is to ensure that a baseline set of environmental and health effects data on 2,800 High Production Volume (HPV) chemicals is made available to the public. EPA believes that the availability of this information is vitally important so that the public can better understand chemical hazards in their communities, homes, and workplaces. Such data will also enable the government, industry, and the public to better understand chemical hazards, and will provide EPA with more complete data upon which to make decisions about priorities for possible future regulation.

EPA is taking concerns about animal welfare seriously in implementing the HPV Challenge Program. As described below, the HPV Program has been designed to reduce the number of chemicals for which testing may be required. Where additional testing is needed, EPA recommends the use of procedures which reduce animal usage by 68 to 80 percent.

Under the HPV Challenge Program, chemical producers and importers are invited to voluntarily provide basic human health and environmental effects data for their HPV chemicals; i.e., those produced or imported into the United States in quantities exceeding one million pounds per year. Data on chemicals which are not voluntarily sponsored would be obtained under regulations issued by the Agency. Sponsors of HPV chemicals will identify and assess the adequacy of existing data; design and submit test plans which identify existing data as well as data needs; conduct needed testing only where adequate data do not exist; and, provide the test results to EPA and the public in the form of robust summaries. To facilitate these efforts, the Agency has developed and continues to develop guidance for use under the HPV Challenge Program.

## Efforts to Reduce Animal Testing

In implementing the HPV Challenge Program, EPA is committed to examining alternative test methods that reduce the number of animals for testing, that reduce pain and suffering of test animals, and that replace animals in testing with *in vitro* (non-animal) test systems. The Agency encourages companies to consider approaches that can reduce the amount of testing needed. Companies have the opportunity to develop and submit plans for testing chemical categories, which involves selecting a subset of the chemicals for testing as representative of an entire class or group of chemicals. Other approaches using existing data can be used both to help define categories and to help assess closely related chemicals.

## Types and Validity of Data to be Collected

The Screening Information Data Set (SIDS) represents an internationally agreed upon set of test data needed to screen HPV chemicals and identify potential hazards. These include studies for physical chemical properties (e.g., water solubility), environmental fate (e.g., biodegradation), environmental toxicity to fish and other aquatic species, and mammalian toxicity (acute toxicity, genetic toxicity, repeat dose toxicity, and reproductive and



developmental toxicity). Any needed testing under the HPV Challenge is to be conducted using test guidelines that are recognized and accepted by governments and scientists worldwide as providing high quality, screening level test data.

#### **The Role of Existing Test Data**

The HPV Challenge Program was prompted by the results of independent studies conducted by EPA, the Environmental Defense Fund (EDF), and the Chemical Manufacturers Association (CMA). These studies reached the same conclusion: there is a significant lack of basic hazard screening data available for a large percentage of HPV chemicals. EPA recognizes that additional data are likely to exist in information sources beyond those searched by EPA, EDF, and CMA. EPA encourages industry and others to search for relevant existing and valid data, and to share the sources of such information. Chemicals for which adequate SIDS data already exist will not be retested under the HPV Program. In addition, all test plans submitted by companies will be posted on the Internet for a 90-day review period prior to the start of testing. During this period, sponsors will be asked to delay the conduct of needed tests. This will provide an opportunity for the identification of valid existing data which may not have been cited and for the recommendation of alterations to the test plans which could reduce the need for additional animal testing. Through these steps, EPA is working to minimize needed testing.

*For more information on the specific actions EPA is taking to reduce the use of animals in the HPV Challenge Program, or general information about the Chemical Right-to-Know Initiative, please visit our web site at: [www.epa.gov/chemrtk](http://www.epa.gov/chemrtk) or call (202)260-3951.*

#### **Scientific Validation of Alternative Non-Animal Testing**

Scientific validation is an essential step in determining the adequacy of new alternative test methods. Validation consists of ensuring that a new method is (1) relevant to the identified need, (2) adequate to meet that need, and (3) reproducible. Peer review to determine the level of validation of alternative protocols is performed by various recognized authorities such as the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the European Centre for the Validation of Alternative Methods (ECVAM), and the Organization for Economic Cooperation and Development. Following the recommendations of such organizations, federal agencies then decide whether to adopt alternative test methods for their regulatory purposes.

Until non-animal test methods are validated and achieve regulatory acceptance, these methods cannot be relied on as alternatives to established test guideline studies for purposes of the HPV Challenge Program. Unfortunately, with the exception of genetic toxicity, no methods relevant to data sought under the SIDS program have been validated and accepted by *any* recognized authority or regulatory body, domestically or abroad. Thus more work is needed before these methods would be acceptable for use under the HPV Challenge Program. EPA is working with the organizations listed above, and others such as the Johns Hopkins University Center for Alternatives to Animal Testing, to identify, validate, and peer review potential alternative protocols, and to ensure the scientific and regulatory acceptability of the tests. If relevant alternative test methods become validated and achieve regulatory acceptance during the implementation of the HPV Challenge Program, EPA will consider their immediate implementation in the program. To enhance the use of alternative testing methods, EPA will continue to involve animal welfare interest groups in a constructive dialogue to identify and develop such methods.

#### **Use of Animals in Testing HPV Chemicals**

EPA is taking a number of important steps to address animal welfare issues in the HPV Challenge Program. EPA recommends the use of an alternative to the LD50 test that reduces the number of rodents needed by 60 percent. EPA has reevaluated its preference for the rodent genetic toxicity test and will accept other non-animal studies. EPA also recommends the use of combined studies and specific actions to reduce pain and distress in test animals. Taken together, the measures that EPA has recommended would reduce animal usage by 68 to 80 percent. EPA will communicate these testing recommendations to sponsors of HPV chemicals.